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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,604	CORONEO, MINAS THEODORE	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 10-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's Response filed January 20, 2004 to the Request for an Election of species is acknowledged. Applicant has elected with traverse the single species Gadolinium.

The traversal is on the grounds that the species are linked by the generic property that they block stretch-activated channels of eye retinal ganglion cells. Applicant urges a reasonable number of species are presented in the claims.

Applicant's arguments have been given consideration but are not found persuasive. A plethora of compounds that are structurally unrelated is encompassed in claims 11 and 14. The required search is based on species, not broad generic types of compounds. For example, a search of aminoglycoside antibiotics involves gentamicin, amikacin, kanamycin, etc. Distinctness of the methods is evidenced by the different classification of the methods and compositions based on the different structure of the compounds. Further, as to the burden of the search, classification is merely one indication of the burdensome nature of the involved search. The literature search of the large number of possible compounds claimed herein is not necessarily co-extensive and is a major factor. The number of species presented is not reasonable. An election of a single disclosed species is still deemed proper and is adhered to.

Accordingly, the subject matter presently under consideration are those methods and compositions comprising Gadolinium for the treatment of glaucoma, claims 3 and 10-14. Those methods and compositions comprising other compounds are withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected

inventions. Re-affirmation of the election of species is requested when Applicant responds to this Office Action.

A Preliminary Amendment filed October 18, 2002, is further acknowledged. Claims 1, 2 and 4-9 are canceled. Claims 3 and 10-14 remain under consideration.

An Information Disclosure Statement filed October 18, 2002 is further acknowledged. The parent application S.N. 09/649643 was obtained. However, none of the references therein cited was present in the file. Those references that are readily retrievable by the Examiner have been presently reviewed.

The disclosure is objected to for the following informalities: A word or term is missing in claim 1, line 4, between "to" and "retinal".

Claim 14 recites "The method of claim 12". Claim 12 is a composition claim.

Appropriate correction is required.

Claims 3 and 10-14 are rejected under judicially created doctrine as being drawn to an improper Markush group. The members of a proper Markush group must share a common utility and a substantial structural feature disclosed as being essential to that utility. Lack of unity of invention has been found to exist since a common nucleus among the various disclosed compounds that block stretch-activated channels of eye retinal ganglion cells or other pressure sensitive retinal ganglion cellular mechanisms is absent. A prior art reference anticipating the claims under 35 U.S.C. 102 with respect to one species, as cisplatin, for example, would not render the same claims obvious under 35 U.S.C. 102 with respect to another species, as Gadolinium. The members of the

instant Markush group possess widely different properties and are not considered functionally equivalent.

Deletion of the non-elected subject matter would resolve the issue.

The claims are examined fully with respect to the elected species only and further to the extent necessary to determine patentability. See MPEP 803.02.

Claims 3 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as lacking a clear written description of the invention and of the manner and process of practicing it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the same, and, not setting forth the best mode contemplated by the inventor to carry out the invention.

Claims 3 and 12 recite "other pressure sensitive mechanisms of retinal ganglion cells". The specification fails to define any such mechanisms. One skilled in the art finds no guidance with respect to therapeutic applications in the form of a definitive treatment of glaucoma wherein "other mechanisms" are affected by the administration of Gadolinium. There is no showing that Applicant had possession of the claimed invention of treatment of glaucoma involving "other mechanisms". The present level of skill in the ophthalmology art would reasonably require a more detailed written description directed to the means of carrying out the claimed methods wherein "other pressure sensitive retinal ganglion cellular mechanisms" are involved.

Claims 3 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention. The claims are directed to the treatment of glaucoma and compositions thereto. The specification provides neither support for the administration of Gadolinium for treatment of glaucoma nor support for compositions comprising Gadolinium as an eye drop or systemic preparation.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treatment of glaucoma comprising administering a composition as ocular drops or a composition for systemic administration.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in ophthalmology.

Each type of glaucoma has its own specific characteristics and etiology. The broad recitation directed to administering "at least one compound which blocks stretch-activated channels of eye retinal ganglion cells or other pressure sensitive retinal ganglion cellular mechanisms" is inclusive of many agents that presently have no established successful utility for glaucoma.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of numerous compounds allegedly useful in the treatment of glaucoma.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples showing efficacy of Gadolinium, nor any other compound, as well as compositions comprising Gadolinium for ocular or systemic administration.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to the preparation of compositions comprising Gadolinium for ocular or systemic administration or the best mode of carrying out the method for the treatment of glaucoma. The skilled artisan would expect

the administration of Gadolinium in the treatment of glaucoma to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for its administration. The instant specification sets forth neither guidelines nor the means for preparing a composition comprising Gadolinium for ocular or systemic administration. Absent reasonable *a priori* expectations of success for using a particular compound to treat any particular type of glaucoma, one skilled in the ophthalmology art would have to test extensively many compositions of compounds, such as Gadolinium, to discover which type responds to that particular composition. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim12 is rejected under 35 U.S.C. 102(b) as being anticipated by Calabrese et al., European Journal of Neuroscience.

Calabrese teaches a composition comprising Gadolinium with one or more excipients. See the end of the third full paragraph, second column, under Solutions on page 2276. The intended use of composition claims confers no patentable weight to the claim. See In re Hack, 114 USPQ 161.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 571-272-0585.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

April 15, 2004